K031817

JUL 17 2003

WRIGHT.

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of CELLPLEX™ TCP Synthetic Cancellous Bone.

Submitted By:	Wright Medical Technology, Inc.
Date:	June 11, 2003
Contact Person:	Ehab M. Esmail Senior Manager of Regulatory Affairs Phone: 901-867-4732 Fax: 901-867 4630
Proprietary Name:	CELLPLEX™ TCP Synthetic Cancellous Bone
Common Name:	Bone Graft Substitute
Classification Name and Reference:	Filler, Calcium Sulfate Preformed Pellets, Unclassified
Device Product Code and Panel Code:	MQV/87

DEVICE INFORMATION

A. INTENDED USE/ INDICATIONS

CELLPLEX™ TCP Synthetic Cancellous Bone can be combined with autogenous bone marrow aspirate and/ or blood and is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. The CELLPLEX™ TCP Synthetic Cancellous Bone is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product resorbs and is replaced with bone during the healing process.

B. DEVICE DESCRIPTION

CELLPLEX™ TCP Synthetic Cancellous Bone is a porous calcium phosphate bone void filler made from tricalcium phosphate for the repair of bony defects. It is osteoconductive with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone. The implant is provided sterile for single patient use. CELLPLEX™ TCP Synthetic Cancellous Bone guides the three-dimensional regeneration of bone in the defect

site into which it is implanted. Pores in the device range from 100 to 400 μm nominally. When CELLPLEX™ TCP Synthetic Cancellous Bone is placed in direct contact with viable host bone, new bone grows in apposition to the calcium phosphate surfaces of the implant, filling the pores with new bone. As the implant is bioabsorbed, bone grows into the space previously occupied by the bone graft substitute.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material composition, and design features of the CELLPLEX™ TCP Synthetic Cancellous Bone are substantially equivalent to the intended use, material composition, and design features of the previously cleared WMT-TCP Bone Graft Substitute (K022629). The mechanical properties of the CELLPLEX™ TCP Synthetic Cancellous Bone are substantially equivalent to the VITOSS™ Scaffold Synthetic Cancellous Bone Void Filler (K994337). The safety and effectiveness of the CELLPLEX™ TCP Synthetic Cancellous Bone is adequately supported by the substantial equivalence information, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2003

Mr. Ehab M. Esmail
Senior Manager of Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002

Re: K031817
Trade Name: CELLPLEX TCP
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: June 11, 2003
Received: June 12, 2003

Dear Mr. Esmail:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WRIGHT.
TM

K031817

CELLPLEX™ TCP Synthetic Bone Substitute
INDICATIONS STATEMENT

CELLPLEX™ TCP Synthetic Cancellous Bone can be combined with autogenous bone marrow aspirate and/ or blood and is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. The CELLPLEX™ TCP Synthetic Cancellous Bone is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product resorbs and is replaced with bone during the healing process.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

Prescription Use ✓
(Per21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031817

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